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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/642,160	08/21/00	HOJGAARD	B 06063.0019

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EXAMINER	
WARE, T	
ART UNIT	PAPER NUMBER
1615	5

DATE MAILED: 06/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/642,160	HOJGAARD ET AL.	
	Examiner	Art Unit	
	Todd D Ware	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 January 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-37* is/are rejected.

7)☒ Claim(s) *18-21, 22-26, 30, and 37* is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Receipt of declaration and fee filed 1-2-01 and information disclosure statement also filed 1-2-01 is acknowledged.

Claim Objections

1. Claims 18-21, 22-26, 30, and 37 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and can not depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

2. Claims 18 and 19 are also objected to because of the following informalities: claim 18 depends from 19, which depends from 18. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 17-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of conditions, diseases, and disorders resulting from oxidative stress, does not reasonably provide enablement for prevention of conditions, diseases, and disorders resulting from oxidative stress. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Prevention of oxidative stress is not enable by the specification as prevention suggests

that 100% of the oxidative stress would be blocked and it is submitted that it would be impossible to completely block the oxidative stress..

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)), the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation; (b) the amount of guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the predictability of the prior art; (g) the breadth of the claims; and (h) the relative skill in the art.

(a) In order to utilize the system as claimed, the skilled artisan would be presented with an unpredictable amount of experimentation. An undetermined number of experimental factors utilizing the instant compositions for prevention of oxidative stress conditions would have to be resolved by the practitioner for the reasons discussed below.

(b & c) The specification states that compositions of the invention can be used to prevent oxidative stress. However, the specification lacks a reasonable level of guidance for a method for said treatment, and working and/or prophetic examples demonstrating prevention of oxidative stress are absent. Applicant has not taught or defined how the invention arrives at preventing oxidative stress in each and every cell.

(d) The nature of prevention of oxidative stress is complex.

(e & f) Although the art provides a certain level of guidance with regards to the use of the instant compositions to treat oxidative stress, these teachings do not provide

sufficient guidance where the specification is lacking. Most notably, the specification does not demonstrate 100% prevention of oxidative stress in each and every cell.

(g) The claims are broad because there is no guidance for the appropriate administration of the instant compositions that would treat oxidative stress in each cell.

(h) The level of skill of those in the art involving prevention of oxidative stress is high.

The skilled practitioner would first turn to the instant specification for guidance in using the compositions for prevention of oxidative stress, as claimed. However, the specification does not provide sufficient guidance for using the instant compositions, as claimed. As such, the skilled practitioner would turn to the prior art for such guidance. However, the prior art demonstrates that treatment of oxidative stress with vitamin C/vitamin A compositions.. Finally, said practitioner would turn to trial and error experimentation to use the instant compositions for prevention of oxidative stress, without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

6. Claims 1-27, 28-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. The term "high " in claim 1 is a relative term which renders the claim indefinite. The term "high" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Therefore, "concentrations" has been rendered indefinite.

8. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 5, 8-11, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 28, 29, 30, 31, 32, 33, 35, 37 recite broad recitations, and these claims also recite amounts within these broad recitations that are narrower statements of the range/limitation.

9. Regarding claims 5, 8-11, 13, 15, 16, 18, 19, 20, 22, 23, 25, 26, 29, 30, 31, 32, 33, and 37, the phrase "such as" renders the claim indefinite because it is unclear

whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

10. Regarding claims 15-16, the phrase "in general" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "in general"), thereby rendering the scope of the claim(s) unascertainable.

11. Regarding claims 5, 8-11, 13, 15, 17, 18, 19, 20, 23, 24, 25, 26, 28, 29, 30, 31, 32, 33, 35, and 37, the phrases "preferably" or "especially" or "most preferably" or "preferably about" or "particularly" render the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

12. Regarding claims 15-16, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

13. Claims 34-37 provide for the use of a vitamin C and vitamin E composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

14. Claims 34-37 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rej ctions - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless –**
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1-16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Valducci (EP 0 820 703; hereafter '703).

'703 discloses oral prolonged-release vitamin C/ rapid-release vitamin E formulations. The amount of vitamin C ranges from about 120 mg to about 1500 mg and the amount of vitamin E ranges from about 300 to about 500 mg (Examples). Since the compositions of '703 appear to be the same as those of the instant claims, they would have the same plasma profile, absent a demonstration otherwise. The process limitations of claims14-16 are not afforded any patentable weight as they are intended uses of the compositions.

17. Claims 1-11, 13-16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by DeFelice (5,560,928; hereafter '928).

'928 discloses oral vitamin C/vitamin E formulations, wherein the vitamin C and vitamin E are in both controlled release and immediate release formulations. The amount of vitamin C ranges from about 0.01 grams to about 3.0 grams and the amount of vitamin E ranges from about 6.7 mg to about 2013.4 mg. Since the compositions of '928 appear to be the same as those of the instant claims, they would have the same

plasma profile, absent a demonstration otherwise. The process limitations of claims 14-16 are not afforded any patentable weight as they are intended uses of the compositions.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valducci (EP 0 820 703; hereafter '703).

'703 teaches oral prolonged-release vitamin C/ rapid-release vitamin E formulations. The amount of vitamin C ranges from about 120 mg to about 1500 mg and the amount of vitamin E ranges from about 300 to about 500 mg (Examples). Since the compositions of '703 appear to be the same as those of the instant claims, they would have the same plasma profile, absent a demonstration otherwise. If shown otherwise, it is the position of the examiner that adjustment of the dose of either vitamin would be within the ken of one skilled in the art to provide greater doses of vitamins in the instance where greater doses are needed such as in someone who is malnourished. The process limitations of claims 14-16 are not afforded any patentable weight as they are intended uses of the compositions.

20. Claims 1-11, 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeFelice (5,560,928; hereafter '928).

'928 teaches oral vitamin C/vitamin E formulations, wherein the vitamin C and vitamin E are in both controlled release and immediate release formulations. The amount of vitamin C ranges from about 0.01 grams to about 3.0 grams and the amount of vitamin E ranges from about 6.7 mg to about 2013.4 mg. Since the compositions of '928 appear to be the same as those of the instant claims, they would have the same plasma profile, absent a demonstration otherwise. If shown otherwise, it is the position of the examiner that adjustment of the dose of either vitamin would be within the ken of one skilled in the art to provide greater doses of vitamins in the instance where greater doses are needed such as in someone who is malnourished. The process limitations of claims 14-16 are not afforded any patentable weight as they are intended uses of the compositions.

21. Claims 17-37are rejected under 35 U.S.C. 103(a) as being unpatentable over Valducci (EP 0 820 703; hereafter '703) in view of Sato et al (1993) or Valducci (EP 0 820 703; hereafter '703) in view of Niki (1986).

'703 is relied upon for all that it teaches as stated previously. '703 does not teach the instant methods of using the compositions for treatment of oxidative stress disorders.

Sato et al teaches that vitamin A and vitamin C interact synergistically to decrease oxidation of neurons in conditions of oxidative stress.

Niki teaches that vitamin A and vitamin C interact synergistically to decrease oxygen toxicity and subsequent occurrence of heart disease, rheumatoid arthritis, inflammatory disorders, cancer, and aging.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to use the compositions of '703 to treat oxidative stress with the motivation of maintaining high concentrations of vitamins C and E as vitamin C is otherwise rapidly eliminated by an organism to treat oxygen toxicity of neurons or peroxidation of biological molecules and tissues.

22. Claims 17-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeFelice (5,560,928; hereafter '928) in view of Sato et al (1993) or DeFelice (5,560,928; hereafter '928) in view of Niki (1986).

'928 is relied upon for all that it teaches as stated previously. '928 does not teach the instant methods of using the compositions for treatment of oxidative stress disorders.

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Accordingly, it would have been obvious to one skilled in the art at the time of the invention to use the compositions of '703 to treat oxidative stress with the motivation of maintaining high concentrations of vitamins C and E to treat oxygen toxicity of neurons or peroxidation of biological molecules and tissues.

Conclusion

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on 7:30 AM - 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

THURMAN K. PAGE
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TECHNOLOGY CENTER 1600

tw
June 13, 2001